OCT 2 2 2001

EXHIBIT #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K013059

1. **Submitter's Identification:**

   Stony Brook Surgical Innovations ("SBSI")
   25 Asharoken Avenue
   Northport, NY 11768

   Contact: Mr. Marc Leahy

   Date Summary Prepared: August 23, 2001

2. **Name of the Device:**

   Stony Brook Surgical Innovations Sterna-Wire (Sternal Sutures)

3. **Predicate Device Information:**

   Ethi-Pack™ Surgical Stainless Steel Suture,
   Ethicon, Inc., Somerville, NJ, K#931271

4. **Device Description:**

   Sterna-Wire is indicated for use in the Sternal Closure. Sterna-Wire is a non absorbable sterile surgical suture composed of 316L stainless steel. The wire material consists of 18" (45cm) 316L stainless steel surgical suture wire and the needle material is a 420 stainless steel sharp semi-circular needle, sterile, non-absorbable, single use. The product will be packaged as 2 wires, 2 sterna-band and 4 wires, 4 sterna-band and 2 wires, and 2 sterna-band products.

5. **Intended Use:**

   The Stony Brook Surgical Innovations' (SBSI) Sterna-Wire is a non-absorbable Stainless Steel Wire with an attached needle that is used during thoracic surgery to close and hold the sternum after a median sternotomy. The Sterna-Wire remains in the Sternum indefinitely and is not removed.

6. **Comparison to Predicate Devices:**

The wire material (18" 316L Stainless Steel Wire) and the needle material (420 Stainless Steel Sharp Semi Circular Needle) are identical between subject and predicate devices. Packaging for both devices consists of cardboard sleeve and tyvek pouch. Sterilization for both devices is by ETO and intended use for both devices is median stenotomy closure. The Ethipak device is packaged in 2, 4 and 6 units, whereas the subject device is packaged in 2 units per package or 2, 4/1 units with the Sterna-Band product.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

- USP 21 Stainless Steel Suture Monographs, Modified
- ASTM F899 Standard Designations
- AAMI/ANSI/ISO 11137 ETO Sterilization Requirements

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. **Conclusions:**

The subject device, Stony Brook Surgical Innovations Sterna-Wire, has the same intended use and characteristics as the predicate device, the Ethi-Pack™ Surgical Stainless Steel Suture. Moreover, bench testing contained in our submission and non-clinical testing supplied demonstrates that there are no differences in their technological characteristics, thereby not raising any new questions of safety or effectiveness. Thus, the Stony Brook Surgical Innovations Sterna-Wire is substantially equivalent to the predicate device, the Ethi-Pack™ Surgical Stainless Steel Suture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 2001

Stony Brook Surgical Innovations
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K013059
Trade/Device Name: Sterna-Wire
Regulation Number: 21 CFR 878.4495
Regulation Name: Stainless steel suture
Regulatory Class: Class II
Product Codes: GAQ
Dated: September 7, 2001
Received: September 11, 2001

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

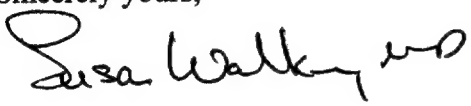
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K013059

Device Name: Stony Brook Surgical Innovations ("SBSI") Sterna-Wire

Indications For Use:

The Stony Brook Surgical Innovations' (SBSI) Sterna-Wire is a non-absorbable Stainless Steel Wire with an attached needle that is used during thoracic surgery to close and hold the sternum after a median sternotomy. The Sterna-Wire remains in the Sternum indefinitely and is not removed.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ **(Per 21 CFR 801.109)** **OR** **Over-The-Counter Use** ____ **(Optional Format 1-2-96)**

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013059